Rep. Debbie Mucarsel-Powell
U.S. House of Representatives, Florida District 26
P.O. Box 56642
Miami, Florida 33256
(305) 222-0160

May 11, 2020

Mrs. Meagan Hull
19585 Date Palm Drive
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Re: Letter of Inquiry to the EPA

Dear Rep. Debbie Mucarsel-Powell,

I am writing to you today with an urgent request to please inquire of the United States Environmental Protection Agency regarding the approval of an experiment of genetically modified mosquitoes in the Florida Keys as early as this summer, only a month away.

Please investigate the May 1st, 2020 approval of the Oxitec application for an experimental use permit (EUP), Federal Register Number 2019-19665, with consideration to the following points of concern:

1. Of the 31,235 comments received and posted to the Regulations.gov website, 31,179 of these comments are "strongly opposed" to this experiment; 56 comments represent "in favor of." Did EPA officials even read the comments?

2. The epa.gov website clearly lists the "Five Principles" that guide their decision making policy. During the open public comments period, a mere two-page document was posted to the regulatory site for public review and response. On the date of the announcement of the approval, May 1, 2020, several additional documents were posted to the site, none of which could be commented upon, because this occurred well over six months after the closure of the public comments period on October 11, 2019. This indicates a lack of fair process, and a lack of transparency in a federal regulatory review process. Additionally, formal requests to extend the public comments period for an additional 60 days were denied, yet the approval process consumed nearly seven months.

3. The epa.gov website also defines "biopesticide," of which this artificially modified subspecies of an invasive species, OX5034, does not qualify, by definition.

4. There currently exists no sufficient regulatory framework in the United States to manage oversight of biotechnology. These are life forms, species, living and evolving, also patented. A "biopesticide" is an entirely different living, propagating weapon. It cannot be contained if there is a "spill." It cannot be rescinded nor remediated once released. Research conducted in Brazil in a previous test area proves that the genes persist in the environment, which could not occur if "only sterile males" were released, as marketed by the corporate entity, Oxitec. Please reference article document attached.

5. Oxitec publicly admitted that a small percentage of mosquitoes will be released, due to an imperfect gender sorting system. The corporate marketing continues to purport, "only males will be released." Please reference FDA report attached, 2016, Page 39.

6. What, if any, coordination was employed during the approval process, between the EPA and the National Institute of Health? Did the EPA reach out at all to seek advice or information, regarding this proposed disease-reducing technology? This is clearly a health issue as well as an environmental issue.

    a. Where are the studies on impacts of biting female mosquitoes on vulnerable populations, such as the elderly, pregnant women, children and people with disabilities or chronic health conditions? There are no safety studies to date.

    b. Where are the studies on impacts of this genetically modified subspecies of invasive species on the COVID-19 virus? We understand viruses mutate and evolve. Where are the studies proving this will not create a new vector? Whereas experts agree that transmission of COVID-19 via genetically modified Aedes aegypti may be a "remote possibility," there exists no body of research specifically addressing this theory. There are no safety studies to date.

    c. Spread of antibiotic resistant bacteria: tetracycline use in rearing the OX5034 mosquitoes is of potential consequence to the spread of antibiotic resistance in the environment and in humans. This is a dire concern to community physicians, as elocuted and visible in the public comments by local physicians on the regulatory website during the public comments period. There are no safety studies to date.

7. Regarding informed consent in a human trial: please provide evidence of written, informed consent of all the individuals in the proposed trial area? Anything less than full, informed, written consent is in violation of basic human rights as per, the Nuremburg Code and the Precautionary Principle.

8. Where is the Environmental Impact Study (EIS) for this product? Is there a standard by which endangered species will be protected? There are none.

In 2011 when I initially learned of this technology, I was impressed and I loved the idea that this new technology might reduce toxic spraying of adulticides and larvicides over our homes, schools, hospitals and offices.

Then I learned that the spraying of pesticides *will continue* with the release of these mosquitoes. There is no silver bullet, no golden ticket that will resolve all of our nuisance species in this world. However, the ways in which we screen products for safety is so very important for the health of our communities and the environment. Technically correct processes and procedures, for the good of all people, are critical in ethical regulatory oversight.

This time sensitive request is relevant to our community. The decision of local mosquito control to conduct this trial rests upon a referendum vote from four years ago. Many of those residents no longer live in the Florida Keys. Many new residents now reside here. There are so many emergent issues of concern with the process as well as the technology in this case. Are we to simply ignore a Change.org petition created by the late Mila DeMier, of over 231,479 signatures (increasing daily) opposing this technology?

Thank you in advance for your consideration.

Respectfully,

Meagan Hull